DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

August 25, 2003

WARNING LETTER
CH-19-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William H. Jenner, President
Lincoln Land Livestock Co., Inc.
436 South Railway Ave.
Mascoutah, Illinois 62258

Dear Mr. Jenner:

On April 14 and 15, 2003, the Food and Drug Administration (FDA) conducted an inspection at your animal feed handling facility at 436 South Railway Ave., Mascoutah, Illinois, that, among other things, operates as an own label distributor of "Hot Line" brand feeds made for you by [redacted] The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 (21 CFR 589.2000) – **Animal Proteins Prohibited** in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being handled by your facility to be **misbranded** within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also found significant deviations from the requirements set forth in 21 CFR 501 – Animal Food Labeling.

Our investigator found the following violations during the inspection:

- Products that contain or may contain prohibited material fail to bear the caution statement – "**Do not feed to cattle or other ruminants**" as required by 21 CFR 589.2000(c)(1)(i). Specifically, your firm is responsible for preparing the formulations and labeling for Lincoln Land labeled products and some of the products lack the above required cautionary statement.

- Product ingredients are not listed on the label of the product Hotline Sow 100 by common or usual name in descending order of predominance by weight as required by 21 CFR 501.4. Also, the ingredient list on the label does not reflect all the ingredients.

During the inspection FDA's investigator also found that you did not maintain written clean-out procedures to prevent carryover of protein derived from mammalian tissues to animal protein or feeds that may be used for ruminants. You had no written procedures that describe the steps used to clean your truck after hauling bulk meat and bone meal. 21 CFR 589.2000 requires maintenance of written clean-out procedures.

The above is not intended to be an all-inclusive list of violations. While you handle the animal feed label and distribution operations, the products manufactured for you are directed, through contract arrangement with the above mentioned [redacted] Your firm, as the handler and labeler of materials intended for animal feed use, is responsible for controlling your part of the operation to ensure that the products manufactured are in compliance with the law.

You should take prompt action to correct all of these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure, and/or injunction.

Please provide this office within 15 working days of receipt of this letter the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations, and prevent their recurrence. Please include copies of any available documentation such as written procedures, corrected labeling, etc. demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the above letterhead address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director